REMARKS

Claims 1-36 and 50-58 stand rejected. Applicant requests reconsideration and allowance in view of the amendments and remarks herein.

Applicants have amended claims 1, 22, 26-28, 50 and 58. Claims 29 and 51 have been cancelled. Claims 37-49 have been withdrawn as drawn to a non-elected invention. New claims 59-63 have been added.

Claims 1, 22, 27-28 and 50 have been amended to recite that the plants are male-sterile due to cytoplasmic male sterility, nuclear male sterility or genetic male sterility. Claims 27-28 and 50 have been amended to recite that the sequence to be transcribed is a pharmaceutical or industrial polypeptide. Claim 26 has been amended to correct an inadvertant error in claim dependency. Support for these amendments is found, for example, at page 26, lines 12-14 and page 13, lines 19-22 of the specification.

New claims 59-60 depend from claim 50 and recite the presence of additional nucleic acids in the claimed plant. Support for these claims can be found, for example, at page 13, lines 5-15. New claims 61-63 depend indirectly from claim 50 and recite particular plant genera. Support for these claims can be found at page 26, lines 6-8.

Provisional Double Patenting

The Examiner has provisionally rejected claims 1-36 and 50-58 for obviousness-type double patenting over copending Application No. 10/873,679. Applicant respectfully requests that this rejection be held in abeyance until claims in the instant application are otherwise found to be allowable. Application No. 10/873,679 is a continuation-in-part of the instant application. Applicant also notes that Application No. 10/873,679 was filed on June 22, 2004 and thus is not prior art to the instant application.

Rejections Under 35 USC § 112

Written Description

The Examiner has rejected claims 1-36 and 50-58 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner asserted that "the specification only provides guidance for plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain. No guidance is presented for the isolation or characterization of any other transcription activator-encoding sequences or any other transcription activator recognition sequences, or plants transformed therewith." Office Action at page 3. The Examiner quoted from Lilly, which stated that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The Examiner also asserted that there was a "lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith," and a lack of written description of the resultant products. Office Action at page 5.

Applicant respectfully traverses.

Compliance with § 112 written description requires sufficient information in the specification to show that the inventor possessed the invention as of the filing date. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). ("[T]he applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."); Union Oil Co. of Cal. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" (citation omitted)). Written description is judged from the perspective of one of ordinary skill in the art as of the relevant filing date. See Vas-Cath, 935 F.2d at 1563-64.

The Court of Appeals for the Federal Circuit has recognized that disclosure of specific known sequences is not a *per se* requirement for satisfying written description. The Court stated

in Capon v. Dudas that "[w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh." Capon v. Eshhar v. Dudas, 03-1480, 1481 at 15 (Fed. Cir. Aug. 12, 2005). More recently, the Federal Circuit has held that "(1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met [ ] even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." Falkner v. Inglis, 448 F.3d 1357, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006). In particular, the Federal Circuit held in Falkner with respect to point (3) that "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." Id. at 448 F.3d 1368.

The amount of guidance in the specification is more closely related to the enablement requirement of § 112 than the written description requirement. To the extent that the amount of guidance is a factor in assessing written description, Applicant submits that the present specification provides more than sufficient guidance to one of ordinary skill. The specification provides a description of transcription activators and their cognate recognition sequences at page 21, lines 1-15. Transcription activators would have been well-known to one of ordinary skill in the art as of the filing date of the present application. For example, de Pater et al. state that "a variety of sequence-specific DNA binding proteins have been studied, that are necessary for inducible or high levels of transcription." de Pater et al., Nucleic Acids Res. 24:4624-4631 (1996) at page 4624, left-hand column. de Pater also state that "[f]or many different plant transcription factors the exact sequence requirement for DNA binding have been determined" and "[s]everal different types of activation domains have been identified and are classified as acidic, glutamine rich or proline rich." de Pater et al. at page 4624, right-hand column. See, also, Struhl, Trends Biochem. Sci. 14:137-140 (1989) and Meshi and Iwabuchi, Plant Cell. Physiol. 36:1405-1420 (1995). In addition, one of ordinary skill would have been aware of chimeric

transcription activators from various publications. See, e.g., WO 97/31064 at page 3, last paragraph; Bruce et al., Plant Cell 12:65-79 (2000) at page 76, left-hand column, second paragraph; and U.S. Patent 6,063,985 at column 6, lines 3-38. Copies of these articles are in the supplemental IDS submitted herewith.

Rather than mechanically reciting a list of transcription activators and recognition sequences that can be introduced into a plant, Applicant has described this class in words that one of ordinary skill would have clearly understood. It is submitted that one of ordinary skill would not have questioned why Applicant did not mechanically recite a list of specific transcription activators and recognition sequences, and would have appreciated Applicant's clear, concise language. The Federal Circuit has stated that the written description requirement may be satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed.Cir.1997) "Certainly no length requirement exists for a disclosure to adequately describe an invention. . . . [T]he adequacy of the description . . . depends on its content in relation to the particular invention, not its length." See, In re Hayes Microcomputer Products, Inc. Patent Litigation (Ven Tel, Inc. v. Hayes Microcomputer Products, Inc.), 982 F.2d 1527 (Fed. Cir. 1992). Accordingly, as the standard for written description is assessed from the viewpoint of one having ordinary skill in the art, transcription activators and recognition sequences that can be introduced into a plant and methods involving the same have more than adequate written description in the specification as filed.

Methods of using such transcription activators such as transforming them into plants are clearly described in the specification. See, e.g., specification at page 25, lines 16-21 and page 28, lines 28-33.

In view of the above, Applicant respectfully requests that the rejection of claims 1-28, 30-36, 50 and 52-58 for lack of written description under 35 U.S.C. § 112, first paragraph, be withdrawn.

Enablement

The Examiner has rejected claims 1-36 and 50-58 under 35 U.S.C. § 112, first paragraph as lacking enablement. The Examiner asserted that "the specification only provides guidance for plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain. No guidance is presented for the isolation or evaluation of any other transcription activator-encoding sequences or any other transcription activator recognition sequences, or plants transformed therewith." Office Action at page 6. The Examiner asserted that gene modulation in plants using heterologous transcription activators is unpredictable, referring to publications by Lloyd et al. and Schena et al. Office Action at pages 6-7.

Applicant respectfully traverses.

The test for enablement is whether one skilled in the art as of the effective filing date could make and use the claimed invention from the disclosures in the specification coupled with the information known in the art without "undue" experimentation. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Factual considerations that can be weighed when determining whether "undue" experimentation would be required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount of direction or guidance provided, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. See, In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All the evidence must be considered, and any conclusion of nonenablement must be based on the evidence as a whole. MPEP § 2164.01(a).

Applicant respectfully submits that an analysis of all the relevant evidence reveals that the specification as filed is such that one of ordinary skill in the art would have been able to make and use the claimed invention without undue experimentation. As discussed above, the present specification provides more than sufficient guidance regarding transcription activators, which were well-known to one of ordinary skill in the art. de Pater et al., Nucleic Acids Res.

24:4624-4631 (1996); Struhl, Trends Biochem. Sci. 14:137-140 (1989); Meshi and Iwabuchi, Plant Cell. Physiol. 36:1405-1420 (1995); WO 97/31064; Bruce et al., Plant Cell 12:65-79 (2000) and U.S. Patent 6,063,985. These references are discussed above.

The present specification provides detailed guidance regarding the practice of the claimed methods. For example, guidance for practicing methods for making infertile seed is provided at page 16, line 12 to page 13, line 15. As another example, detailed guidance for making and using the claimed plants is provided at page 25, line 16 to page 28, line 8. In view of the extensive knowledge in the art regarding transcription activator coding sequences, transcription activator recognition sequences, and plants transformed therewith, one of ordinary skill would have been able to produce virtually any desired transgenic plant.

The Examiner referred to articles by Lloyd et al. ("Lloyd") and Schena et al. ("Schena") to support the proposition that gene modulation in plants using heterologous transcription activators would have been unpredictable. Office Action at page 6. The Lloyd article relates to two nuclear hormone receptor polypeptides, glucocorticoid receptor (GR) and estrogen receptor (ER). Lloyd, published in 1994, reports that six *Arabidopsis* lines stably transformed with a chimeric polypeptide containing a GR ligand binding domain and maize activation and DNA binding domains showed hormone dependent induction. Lloyd at page 436, middle column. Lloyd also reports that six *Arabidopsis* lines transformed with a chimeric polypeptide containing an ER ligand binding domain and maize activation and DNA binding domains showed hormone dependent induction showed hormone dependent induction. Lloyd at page 436, right-hand column. Lloyd does not state that these lines were not useful. Lloyd merely reports that these lines showed substantial background and were not examined in detail. Moreover, a more recent article by Bruce et al. indicates that one of ordinary skill would have known how to make and use gene modulation using an ER hormone receptor. Bruce et al. report that a chimeric ER-maize C1 polypeptide showed hormone dependent induction in cultured maize cells. Bruce et al. Plant Cell 12:65-79 (2000). Thus, the Lloyd article is not indicative of the state of the art as of the effective filing date of the present application.

The Schena article was published in 1991 and relates to the use of GR to develop an inducible gene expression system in plant cells. Schena refers to an earlier report that the GAL4 protein, the principal activator of the GAL4 promoter, has not been used successfully in plant cells. Schena at page 10422, left-hand column, first paragraph. However, enablement is determined as of the filing date. MPEP § 2164.05(a). Here, the state of the art had advanced from the time Schena was published in 1991 to the time of the effective filing date of the present application, September 17, 2002. For example, WO 97/30164 reports that expression was improved by using a codon-optimized GAL4 coding sequence. See WO 97/30164 at page 11. WO 97/30164 also reports that reporter gene expression accurately reflected the expression of a GAL4-VP16 chimeric transcription activator. Id at page 15. Thus, the Schena article is not indicative of the state of the art as of the effective filing date of the present application, and one of ordinary skill would have been able to use GAL4 as well as other transcription activators as of the effective filing date.

As indicated in §2164.01 of the MPEP, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is undertaken, it is undue. In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). In the present case, making and using the claimed plants and methods is typical of that carried out in the art. In view of the evidence above, one of ordinary skill would have been able to practice the claimed invention using heterologous transcription activators without undue experimentation.

Applicant respectfully requests that the rejection of claims 1-28, 30-36, 50 and 52-58 for lack of enablement under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections Under 35 USC § 102

Rejection of Claims 50-51, 53-54 and 56-58

The Examiner rejected claims 50-51, 53-54 and 56-58 under 35 USC § 102(e) as anticipated by U.S. Patent 6,362,394 to Crossland et al. ("Crossland"). The Examiner asserted that "Crossland et al teach transgenic plants which comprise a first construct: comprising a first GAL4 transcription activator recognition sequence, anther-specific promoter, and barnase

protein-encoding sequence; and a second construct comprising a second GAL4 transcription activator recognition sequence, pistil-specific promoter, and barnase protein-encoding sequence which is capable of conferring seed sterility when expressed specifically in seeds; wherein the first construct confers nuclear and genetic male sterility to the plant; and wherein the plant was obtained by crossing parent plants which each contained a single construct; wherein monocotyledonous maize or dicotyledonous Arabidopsis plants may be obtained." Office Action at page 8. Applicant respectfully traverses.

Claims may be properly rejected as anticipated under § 102 "if each and every limitation is found either expressly or inherently in a single prior art reference. To anticipate, the reference must also enable one of skill in the art to make and use the claimed invention." Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001).

The Crossland reference does not teach each and every limitation of claims 50-51, 53-54 and 56-58, which have been amended to recite that male-sterility is due to cytoplasmic, nuclear or genetic male sterility systems. Crossland discusses the use of USP receptor polypeptides in order to control plant fertility after application of juvenile hormone. See, Crossland at column 2, lines 23-38. However, control of plant fertility in Crossland requires receptor polypeptides that are responsive to a chemical ligand. See, Crossland at column 14, lines 54-58; column 18, lines 24-29. Furthermore, the plants of Crossland are "engineered to be male sterile in the presence of juvenile hormone or one of its agonists" or are "engineered to be male-sterile in the absence of juvenile hormone or one of its agonists . . .." Crossland at column 18, lines 47-49 and 54-56 (emphasis added).

In contrast to Crossland, the presently claimed plants are male-sterile due to, e.g., cytoplasmic, nuclear or genetic male sterility. Cytoplasmic, nuclear or genetic male sterility is structurally different from ligand-responsive sterility, because cytoplasmic, nuclear or genetic male sterility does not involve transgenes, whereas a transgene is required for ligand-responsive sterility. Cytoplasmic, nuclear or genetic male sterility operates whether or not a ligand is present and therefore is functionally different from ligand-dependent sterility.

Since Crossland teaches plants that are male-sterile due to the use of a ligand-responsive receptor rather than plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility, Crossland does not teach each and every limitation of amended claims 50, 53-54 and 56-58. Therefore, Crossland does not anticipate these claims. The Examiner is requested to withdraw the rejection under 35 USC § 102(e) over Crossland.

Rejection of Claims 50-51, 53-54 and 57-58

The Examiner rejected claims 50-51, 53-54 and 57-58 under 35 USC § 102(b) as anticipated by U.S. Patent 6,147,282 to Goff et al ("Goff"). The Examiner asserted that "Goff et al teach transgenic plants which comprise a first construct comprising a first GAL4 transcription activator recognition sequence, anther-specific promoter, and barnase protein-encoding sequence; and a second construct comprising a second GAL4 transcription activator recognition sequence, pistil-specific promoter, and barnase protein-encoding sequence which is capable of conferring seed sterility when expressed specifically in seeds; wherein the first construct confers nuclear and genetic male sterility to the plant; and wherein the plant was obtained by crossing parent plants which each contained a single construct; wherein monocotyledonous maize plants may be obtained." Office Action at page 9.

Applicant respectfully traverses. Goff, as with Crossland, discuss the use of receptor polypeptides in order to control plant fertility after application of a chemical ligand. See, Goff at column 14, line 63 to column 15, line 14.

As discussed above, the presently claimed plants are male-sterile due to, e.g., cytoplasmic, nuclear or genetic male sterility, regardless of the presence or absence of chemical ligands. Thus, there is no need for chemical ligands.

Since Goff does not teach plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility, Goff does not teach each and every limitation of amended claims 50, 53-54 and 57-58, and does not anticipate these claims. The Examiner is requested to withdraw the rejection under 35 USC § 102(b) over Goff.

Rejections Under 35 USC § 103

Rejection of Claims 1-18, 21-36 and 50-58.

The Examiner rejected claims 1-18, 21-36 and 50-58 under 35 USC § 103(a) over Crossland or Goff in view of U.S. Patent 6,781,035 to Harada et al. ("Harada"). The Examiner asserted that "it would have been obvious to one of ordinary skill in the art to utilize the method of crossing plants comprising transcription activator recognition sequences, transcription activator coding sequences, coding sequences conferring seed sterility, and male sterile parent plants as taught by each of Crossland et al and Goff et al; and to modify that method by incorporating seed-specific promoters for the production of infertile seeds in the progeny plants, LEC1 promoters and coding sequences, and dicot transformation as taught by Harada et al; as suggested by each of the references." Office Action at page 12.

Applicant respectfully traverses because the cited references, when combined, do not teach or suggest every element of the claimed invention.

Proper analysis under 35 U.S.C. § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed product, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success. *See, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is axiomatic that in order to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, a prior art reference must teach or suggest, alone or in combination with other prior art references, each and every element of the claimed invention. *See, e.g.*, MPEP § 2143. The Federal Circuit warns that "both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure," and that "it is impermissible to use the claimed invention as a 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *See, In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988) and *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed Cir. 1992).

Both Crossland and Goff are directed to receptor polypeptides that require the use of chemical ligands in order to control fertility. See, e.g., Crossland at column 2, lines 1-51 and Goff at column 2, lines 45-66.

In contrast, the methods of amended claims 1-18 and 21-27 involve the use of plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility. As discussed above, cytoplasmic, nuclear or genetic male sterility is structurally and functionally different from ligand-responsive sterility. There is no specific suggestion whatsoever in Crossland or Goff regarding the use of receptor polypeptides in combination with cytoplasmic, nuclear or genetic male sterility.

In addition, control of plant fertility in Crossland refers to inhibition or prevention of fertilization, i.e., rendering fertilization ineffective. See, Crossland at column 15, lines 1-3 and lines 54-58; column 16, lines 44-46 and lines 47-50. Goff, as with Crossland, discuss the use of receptor polypeptides in order to control plant fertility after application of a chemical ligand. Control of plant fertility in Goff refers to inhibition or prevention of seed formation. See, Goff at column 14, line 63 to column 15, line 14. That is, similar to Crossland, control of plant fertility in Goff involves rendering fertilization ineffective. If fertilization is ineffective, no seeds can be formed. Thus, use of the ligand-dependent receptors as taught by Crossland or Goff leads to an inability to form seeds.

In contrast, the presently claimed methods involve the formation of seeds after carrying out a cross with a plant expressing a transcription activator. See claim 1 preamble, claim 22 step (a), and claim 27 step (b). Such seeds are infertile because they contain a sequence causing seed infertility. As discussed in the specification at page 16, lines 7-16, infertile seeds are seeds that are incapable of producing offspring, e.g., seeds do not germinate, or germinate and form seedlings which do not mature.

Harada does not remedy the deficiencies of the primary references because there is no motivation to combine Harada with either of the primary references and, even if combined, the references do not teach or suggest every element of the claimed invention. Harada discusses inhibition of expression of endogenous LEC1 at column 11, line 29 to column 13, line 23.

However, similar to Crossland and Goff, Harada does not teach or suggest the use of plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility. Harada instead suggests the use of a LEC1 transgene to create sterility. Harada at column 11, lines 34-37. Thus, the combination of Crossland or Goff with Harada results in an invention that is different from the presently claimed methods.

Furthermore, Harada discusses overexpression of LEC1 to induce ectopic embryo morphogenesis. Harada at column 13, lines 26-47; and column 22, line 23 to column 23, line 3. The suggestion of Harada to induce ectopic embryo morphogenesis teaches away from the claimed invention by suggesting that additional embryos be formed to increase, for example, seed mass rather than suggesting that infertile seeds be formed as in the presently claimed methods.

Claims 28-36 as amended relate to an article of manufacture containing seeds that are male-sterile due to cytoplasmic, nuclear or genetic male sterility as well as seeds that are male-fertile. In addition to the reasons discussed above, present claims 28-36 are not taught or suggested by Crossland or Goff when combined with Harada because none of these references specifically teach or suggest the unique composition of cytoplasmically, nuclear or genetically male-sterile seeds mixed with male-fertile seeds, each type of seeds containing the particular nucleic acids recited in the claims.

Claims 50 and 51-58 as amended relate to plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility. Present claims 50 and 51-58 are not specifically taught or suggested by Crossland or Goff when combined with Harada for the reasons discussed above.

In view of the failure of Crossland, Goff and Harada to teach or suggest all elements of the presently claimed invention, Applicant requests that the rejection of claims 1-18 and 21-28, 30-36, 50 and 52-58 under 35 USC § 103(a) as obvious be withdrawn.

Rejections of Claims 19 and 20.

The Examiner rejected claim 19 under 35 USC § 103(a) over Crossland et al. and Goff et al. in view of Harada, further in view of U.S. Patent 6,906,244 to Fischer et al. ("Fischer '244")

and further in view of U.S. Patent 6,229,064 to Fischer et al. ("Fischer '064"). The Examiner rejected claim 20 under 35 USC § 103(a) over Crossland or Goff in view of Harada, and further in view of U.S. Patent 6,559,357 ("Fischer '357"). Applicant respectfully traverses.

The three Fischer patents do not remedy the deficiencies of Crossland, Goff or Harada because there is no specific teaching or suggestion in any of the Fischer patents that one should use plants that are male-sterile due to cytoplasmic, nuclear or genetic male sterility. On the contrary, the Fischer patents merely make general suggestions that FIE, MEA or ANT expression be modulated for the purpose of controlling seed fertility. See, Fischer '244 at column 17, line 58 to column 18, line 9; Fischer '064 at column 9, lines 44-65; and Fischer '357 at column 8, lines 43-59. Thus, the cited references do not specifically teach or suggest every element of the claimed invention even if they were to be combined. In view of the failure of Crossland, Goff Harada, Fischer '244, Fischer '064 and Fischer '357 to specifically teach or suggest all elements of the presently claimed invention, Applicant requests that the rejection of claims 19 and 20 under 35 USC § 103(a) as obvious be withdrawn.

Conclusion

In view of the amendments and remarks above, Applicant respectfully requests reconsideration and allowance of claims 1-18, 21-28, 30-36, 50 and 52-63. Enclosed is a $135.00 check for the Petition for Extension of Time fee and excess claim fees. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: Sep 26, 2006

Ronald C. Lundquist, Ph.D.
Reg. No. 37,875

Fish & Richardson P.C.
60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

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